REMARKS

Notice of Non-compliant Amendment

Applicants thank Legal Instruments Examiner, Ms. Tina J. Barden, for her courtesy and helpfulness in a telephone call with Applicants' undersigned representative on January 6, 2010.

According to the Notice of Non-compliant Amendment dated December 30, 2010, the Response filed December 17, 2009, was non-compliant in that it did not list claim 38 or indicate whether it was pending or cancelled. Ms. Barden indicated in the telephone call with her that, because a Request for Continuing Examination (RCE) had been filed with the Response on December 17, 2009, a supplemental response canceling claim 38 filed prior to January 20, 2010, would be timely filed.

Applicants submit that the failure to list claim 38 in the Response filed December 17, 2009, was entirely unintentional and an inadvertent error that occurred for the following reasons. Claim 38 was added to the application by the law firm previously handling the application in a Preliminary Amendment filed on November 28, 2001. Claim 38 was listed in claim group III in a Restriction Requirement mailed November 9, 2004. The application was at about this time transferred to the present law firm and on January 10, 2005, Applicants' undersigned representative filed a response to the Restriction Requirement electing without traverse the claims of group I (that did not include claim 38) for prosecution in the present application. In three subsequent Office Actions (dated April 7, 2005, February 7, 2008, and November 19, 2008), claim 38 was not indicated to be pending, withdrawn from consideration, or rejected, and indeed was not mentioned at all. As a result, in Applicants' responses of July 21, 2008, June 19, 2009, and December 17, 2009, claim 38 was not listed or mentioned.

The Status of the Claims section below is amended relative to how it read in the Response filed on December 17, 2009, in order to reflect the cancellation of claim 38 herein.

Status of the Claims

Claims 1-15 and 38 are pending and claims 1-15 are under consideration in this application. Claims 1-3, 5, 6, and 9 are rejected. As they are not rejected, Applicants understand that claim 4, 7, 8, and 10-15 are allowable.

Claim 38 is cancelled herein and so, after entry of the amendments made herein, claims 1-15 will be pending and under consideration.

35 U.S.C. § 103(a) rejection

Claims 1-3, 5, 6, and 9 stand rejected as allegedly being unpatentable over Hansbrough et al. Applicants respectfully traverse the rejection.

From the comments on page 1 of the Advisory Action, Applicants understand the Examiner's position to be that, because Hansbrough et al. discloses the use of fibroblasts in the compositions it discloses, the claims are obvious in view of the reference.

Applicants disagree that their prior response was centered on the use of keratinocytes in the methods disclosed by Hansbrough et al. While the article is indeed chiefly concerned with keratinocytes, and only secondarily mentions the fibroblasts together with keratinocytes, Applicants main argument was that the article is focused on the use of sheets of wound repair materials, rather than injectable cell preparations as specified by the claims at issue, and its advantages. In the prior response Applicants provided a detailed description of the relevant disclosure of Hansbrough et al. and arguments why using injectable cell suspensions would not have been obvious in view of the reference. The Advisory Action does not address these arguments. For the convenience of the Examiner, the relevant description and arguments are repeated in only slightly modified form below.

Hansbrough et al. repeatedly points to its authors' belief that the most important requirement for early skin burn wound treatment is early wound closure or coverage (see, e.g., Abstract, first sentence; introduction section, first and subsequent sentences; Comment section throughout). It is implicit and obvious that early wound closure or coverage requires the application to the wound of some sort of sheet or solid structure (e.g., a sheet of cells only, a sheet of matrix material, or a sheet of matrix material with cells attached to it; see, for example, the introduction section Hansbrough et al.). It is also of course self-evident that injection of a

suspension of cells of any type into a wound would not provide the requisite early wound closure or coverage. In this regard, Hansbrough et al. focuses largely on a comparison of its methodology using sheets of matrix material (collagen-glycosaminoglycan; C-CAG) with attached keratinocytes and fibroblasts to other sheet format graft materials (e.g., skin grafts and keratinocyte sheets) (see, e.g., the introduction section; page 2126, last paragraph; page 2127, first and second full paragraphs; and the entire Comment section). Only once, and there only tangentially, does the reference refer to the use of a cell suspension, and in this case, a suspension of keratinocytes (page 2128, last sentence), not fibroblasts. In this and the following sentence it describes the clear advantage of its sheet format cell-matrix compositions over such keratinocyte suspensions as well as keratinocyte sheets. Importantly, nowhere does the reference allude to, even remotely suggest, the use of fibroblast suspensions (as required by the present claims). Thus, one of ordinary skill in the art after reading the Hansbrough et al article would not have considered using a keratinocyte suspension, let alone a fibroblast suspension, for burn wound treatment

With respect to the comment on page 4, lines 14-15, of the Office Action of November 19, 2008, Applicants agree that "[m]any pharmaceutical or bioactive compositions can be given through various formulations." However, as pointed out by Hansbrough et al. and above, injecting keratinocyte suspensions into skin wounds would at the priority date of the present application have been considered by those ordinarily skilled in the art far less likely to be successful than placement of sheet format cell-matrix composites such as those described in the reference and therefore not obvious to do. Most importantly, as indicated above, Hansbrough et al. does not mention or even suggest the possibility of using fibroblast suspensions. Finally, the question posed on page 4, lines 16-17, of the Office Action of November 19, 2008 ("[W]hat is the criticality of the suspension over the sheet of Hansbrough et al?") is answered by Hansbrough et al. itself and the above discussion of the reference.

In light of the above considerations, one of ordinary skill in the art would not have considered it obvious, based on the disclosure of Hansbrough et al., to inject a suspension of any cells (e.g., keratinocytes), let alone fibroblasts, into a burn wound. In addition, if such an artisan had previously considered doing so, the teachings of Hansbrough et al. would have dissuaded him or her and persuaded him or her to rather use the sheet format cell-matrix composite it

describes. Moreover, for the same reasons, in the unlikely event that one of ordinary skill in the art did consider treating a subject with a burn wound by injection of fibroblasts, he or she would in view of the teachings of Hansbrough et al. have had little to no expectation of success.

Therefore, Applicants respectfully submit that one of ordinary skill in the art would not have considered it obvious in view of Hansbrough et al. to perform the methods of the instant claims and hence request that the rejection under 35 U.S.C. § 103(a) be withdrawn.

CONCLUSION

In summary, in view of the amendments and remarks set forth above, Applicants request that the Examiner permit the pending claims to pass to allowance.

If the Examiner would like to discuss any of the issues raised in the Office Action, Applicants' undersigned representative can be reached at the telephone number below.

Please apply any charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket No. 10592-023US1.

Respectfully submitted,

Date: January 8, 2010

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